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4/9/1

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Cardiologists draw - up the dream stent

Clinica 710 p 15, June 17, 1996 (19960617)

Story Type: F Word Count: 466

"Interventional cardiologists are like lazy gardeners, they want something that can be planted and left alone," says pioneering stenter Dr Ulrich Sigwart. "Even better would be a stent that would train the artery then melt away leaving only a footprint," said Dr Sigwart during a round-table discussion on the dream stent. Dr Julio Palmaz thinks there is little mechanical, technical or design work left to do. He believes future developments lie at the high tech end, dealing with surface treatments. "Once you have a radial tyre you can change the tread a million times," he said. But as co-inventor of the best selling Palmaz-Schatz stent, his view comes as no surprise.

Others disagreed, saying there is a real need for lesion specific designs. And while some stents are obviously me-too products angling for a share of what some consider the most exciting medical device market this decade, many new designs clearly aim to keep specific lesions open better than the gold standard - the Palmaz-Schatz slotted stainless steel tube.

Early data for some designs were presented at the American College of Cardiology meeting in Orlando in March, although most of the research is being carried out beyond the reach of the FDA, in Europe (see Clinica No 699, p 16-17).

One design not seen before is a bifurcated stent, the Divysio. Dr David Cumberland of Sheffield University, made what he described as an "embarrassingly preliminary presentation". The device is not yet patented so he was only prepared to show a tantalising picture taken through a pig's artery! The Divysio may not even be bifurcated, suggested Dr Sigwart.

However, he believes a truly bifurcated device would make a real contribution to the treatment of left main artery disease. Manufacture would be complicated, the technology would have to be elaborate and the patient population is small, but there is light at the end of the tunnel, he told Clinica.

Dr Sigwart's dream of the disappearing stent will have to wait until a suitable polymer has been found. He said there is early evidence that there are some very friendly polymers. However, Dr Robert Schwartz of the Rochester Mayo Clinic said that some, supposedly very biocompatible compounds, such as Tecoflex (polyurethane), cause severe reactions when used in coronary arteries. PVC is as well tolerated as metal, while silicone lessens the amount of neointima formation.

coated stents present regulatory nightmare

Dr Martin Leon believes the device and drug trials needed for coated stents will require "tremendous creativity, especially at the US FDA" Heparin is the only coating that does not require a New Drug Application. He believes the FDA will probably accept registry data for new stents, as randomisation against PTCA is unethical in the light of the STRESS and Benestent trials. However, he believes drug coatings will require randomised trials.

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